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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,473	11/08/2001	Michael Hagen	33,482-00	3152

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EXAMINER	
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ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/009,473	HAGEN, MICHAEL	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *88-90,98,105,109,116-119,160,163,164 and 167* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 88-90, 98-119, 127-130, 138-141, 149-152, 160, 162-164, 166-168, 170-171, 173-174, 176-177, 179-180, 182-183 and 185-199.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 99-104, 106-108, 110-115, 127-130, 138-141, 149-152, 162, 166, 168, 170-171, 173-174, 176-177, 179-180, 182-183 and 185-199.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/21/2007 has been entered.

Information Disclosure Statement

2. The information disclosure statement filed 12/21/2007 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because it fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. In the instant case, it appears that PTO-1449 is missing from the 12/21/2007 information disclosure statement submission. A copy of enclosed PTO-1449 is not in file. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Election/Restrictions

3. Applicant's election without traverse of Group I, the adjuvant combination of 3-O-deacylated monophosphoryl lipid A or monophosphoryl lipid A and granulocyte macrophage colony stimulating factor (GM-CSF), in the reply filed on 7/31/2006 is acknowledged.

Status of claims

4. Claims 1-87, 91-97, 120-126, 131-137, 142-148, 153-159, 161, 165, 169, 172, 175, 178, 181 and 184 are cancelled. Claims 186-199 are added. Claims 88-90, 98-119, 127-130, 138-141, 149-152, 160, 162-164, 166-168, 170-171, 173-174, 176-177, 179-180, 182-183 and 185-199 are pending. Claims 99-104, 106-108, 110-115, 127-130, 138-141, 149-152, 162, 166, 168, 170-171, 173-174, 176-177, 179-180, 182-183 and 185 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/21/2004 and 01/28/05. Additionally, claims 186-199 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **with** traverse in the reply filed on

07/31/2006. Claims 88-90, 98, 105, 109, 116-119, 160, 163-164 and 167 are under examination.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 88-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ulrich et al. [1] and Disis et al.[2]

In response to the office action, Applicant argues that Ulrich et al. did not teach or suggest that the immune response to the disclosed combination of antigen and MPL could be enhance by the addition of an immunomodulator, specifically GM-CSF, and that Disis failed to teach or suggest combining GM-CSF with any other adjuvant or cytokine to enhance an immune response to an antigen. Applicant also argues that there is nothing in Ulrich or Disis et al. that would prompt the skilled artisan to combine an antigen with the claimed adjuvant combination of MPL and GM-CSF.

Applicant's arguments filed have been fully considered but they are not persuasive. Applicant is reminded that the claimed invention is not directed at a method of enhancing the immune response induced by MPL and an antigen with the addition of GM-CSF. The claimed invention is directed at a composition consisting of an antigen

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[1] Ulrich et al. Monophosphoryl lipid A as an adjuvant. Past experiences and new directions. In M.F. Powell and M.J. Newman (ed.), Vaccine Design. Plenum Press, New York, NY, p. 495-523.

and an adjuvant, wherein the adjuvant consists of 3-O-deacylated monophosphoryl lipid A or monophosphoryl lipid A, and granulocyte-macrophage colony stimulating factor (GM-CSF), together with a diluent or carrier, and a method of increasing the ability of an antigenic composition containing an antigen to elicit cytotoxic T lymphocytes responses in a host with the administration of the claimed composition to the host. Applicant's arguments do not commensurate in scope with the claimed invention.

Additionally, contrary to Applicant's assertion, Ulrich et al. does teach the combination of antigen and MPL could be enhanced by the addition of an immunomodulator or adjuvant. See first full paragraph on page 510. At the cited passage, Ulrich et al. discloses the synergistic effects of an antigen and MPL with the addition of an immunomodulator or adjuvant on the specific antibody response of mice to a variety of peptide and subunit antigens.

While it is noted that Ulrich et al. does not specifically suggest GM-CSF, the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Ulrich et al. suggests the addition of other adjuvants with MPL and antigen to promote either cytokine and/or cellular activities. And, at the time the invention was made, Disis et al. teaches the use

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[2] Disis et al. Granulocyte-macrophage colony-stimulating factor: an effective adjuvant for protein and

of GM-CSF as an adjuvant. Disis et al. teaches that GM-CSF is a potent adjuvant for the generation of immune responses, both humoral and cell-mediated, to foreign proteins as well as peptide-based vaccines. [Abstract, in particular.] Hence, it would have been prima facie obvious for one of ordinary skill in the art to combine the teachings of Ulrich et al. and Disis et al. with a reasonable expectation of success for doing do because the adjuvant activity of both monophosphoryl lipid A and GM-CSF is well recognized in the art at the time the invention was made.

Furthermore, the courts have established that the rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. Additionally, *KSR* forecloses the argument that specific teaching, suggestion, or motivation is required to support a finding of obviousness. *KSR*, 82 USPQ2d at 1396.

It is noted that Applicant alleges that the Examiner has failed to properly render the claimed invention obvious. That is, Applicant alleges that the Examiner "merely notes how the two references can be combined to read on the claimed invention without an explanation of as to why the skilled artisan would be motivated to combine them.

In response to Applicant's allegation, the Examiner directs Applicant's attention to the rejection itself. Contrary to Applicant's assertion, the rejection provided is not merely a notation of how the two references can be combined. The rejection properly

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peptide based vaccines. Blood, 1996; Vol. 88, no. 1: 202-210.

follows the TSM test and made on the basis of the Graham factual inquiries. As set forth in the rejection, the teachings of MPL and an antigen is found in Ulrich et al. and the teaching of GM-CSF is found in Disis et al. The suggestion to combine the two references is provided by Ulrich et al., who suggests the use of MPL and antigen with other adjuvants. Ulrich et al. discloses the synergistic effects of an antigen and MPL with the addition of an immunomodulator or adjuvant on the specific antibody response of mice to a variety of peptide and subunit antigens. And, at the time the invention was made, Disis et al. teaches the use of GM-CSF as a potent adjuvant for protein and peptide vaccines. And the motivation to combine the teachings of the references is also provided by Ulrich et al. when he teaches that the use of an adjuvant with MPL and antigen provides a synergistic effect. Thus, it would have been prima facie obvious for one of ordinary skill in the art to combine the teachings of Ulrich et al. and Disis et al.

In addition to above, Applicant criticizes the Office for citing In re Kerkhoven. Specifically, Applicant argues that MPL and GM-CSF are not art recognized equivalents of one another. To support Applicant's position, Applicant submitted Exhibits 1 and 2 to demonstrate that adjuvants are very broad class of molecules whose function, mechanism and characteristics differ greatly.

Applicant's submission has been considered, however it is not found persuasive. In re Kerkhoven and MPEP § 2144.06 sets forth that it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for the same purpose. In the instant case, both Ulrich et al. and Disis et al. teaches the use of MPL and GM-CSF as adjuvants. While it is noted that Applicant argues that adjuvants

are very broad class of molecules whose function, mechanism and characteristics differ greatly, however, it should be noted that this argument does not commensurate in scope with the claimed invention. The argument failed to set forth that GM-CSF and MPL differ greatly in function, mechanism and characteristics that one skilled in the art would not recognized the use of GM-CSF and MPL together as an adjuvant. Moreover, it should be noted that both Ulrich et al. and Disis et al. reports the induction of CTL responses by MPL and GM-CSF, respectively. Thus, while MPL and GM-CSF are structurally and are sub-categorically different from one another, it remains that both MPL and GM-CSF are recognized in the art as adjuvants that induces CTL responses. Hence, it would have been prima facie obvious for one of ordinary skill in the art to combine the teachings of Ulrich et al. and Disis et al. for the reason(s) set forth in the office action.

As previously presented, the claims are directed to a composition consisting of an antigen and an adjuvant, wherein the adjuvant consists of 3-O-deacylated monophosphoryl lipid A or monophosphoryl lipid A, and granulocyte-macrophage colony stimulating factor (GM-CSF), together with a diluent or carrier. Claim 89, which depends on claim 88, requires the antigen to be a peptide or protein. Claim 90, which depends on claim 88, requires 3-O-deacylated monophosphoryl lipid A be used in the form of a stable oil-in-water emulsion.

Ulrich et al. teaches the use of monophosphoryl lipid A as an adjuvant to bacterial and viral protein and peptide based vaccines to enhance antibody response to said bacterial and viral protein or peptide. [Pages 509-513, in particular.] Ulrich et al.

also teaches the inclusion of the adjuvant with a carrier. [Section 3.2.1, page 503, in particular.] Specifically, Ulrich et al. teaches the presentation of monophosphoryl lipid A in a stable oil-in-water emulsion. In summary, Ulrich et al. teaches that MPL alone or in combination of other vehicles or immunomodulator provides the appropriate adjuvant activities for a variety of vaccine antigens, including protein and peptide antigens.

However, Ulrich et al. does not teach the inclusion of granulocyte-macrophage colony stimulating factor (GM-CSF).

Disis et al. teaches the use of granulocyte-macrophage colony stimulating factor (GM-CSF) as a potent adjuvant for the generation of immune responses, both humoral and cell-mediated, to foreign proteins as well as peptide-based vaccines. [Abstract, in particular.]

In the instant, both monophosphoryl lipid A and granulocyte-macrophage colony stimulating factor (GM-CSF) are art recognized adjuvants. Therefore, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to combine two art-recognized adjuvants into one composition. [See *In re* Kerkhoven and MPEP § 2144.06 [R-3].] One of ordinary skill in the art at the time the invention was made would have been motivated to do so to enhance the immune response against an antigen of interest. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because the adjuvant activity of both monophosphoryl lipid A and GM-CSF is well recognized in the art at the time the invention was made. Therefore, the claimed invention is obvious over the teachings both Ulrich et al. and Disis et al.

7. Claims 88, 98 and 116-119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ulrich et al. and Disis et al., as applied to claim 88, in view of Bartlett et al.[3]

In response to the rejection, Applicant submits the same arguments presented in paragraph 6 of this office action, which is addressed by the Office in the same paragraph.

As previously presented, claim 98, which depends on claim 88, requires the antigen to be derived from a pathogenic virus. Claim 116, which depends on claim 98, requires the pathogenic virus is human immunodeficiency virus, HIV. Claim 117, which depends on claim 116, requires the HIV antigen be a protein, polypeptide or peptide. Claim 118, which depends on claim 117, further limits the HIV antigen to those having the amino acid sequence set forth in SEQ ID NO: 2. Additionally, claim 119, which depends on claim 116, requires 3-O-deacylated monophosphoryl lipid A to be in the form of a stable oil-in-water emulsion.

The significance of Ulrich et al. and Disis et al., as applied to claim 88, is discussed above. In the instant, neither Ulrich et al. nor Disis et al. teaches an HIV antigen having the amino acid sequence set forth in SEQ ID NO: 2. However, the deficiency noted in Ulrich et al. and Disis et al. is fully compensated by the teachings of Bartlett et al. Bartlett et al. teaches C4-$V3_{MN}$, which has the following sequence: KQIINMWQEVGKAMYATRPNYNKRKRIHIGPGRAFYTTK. [Immunogen design, peptide synthesis and purification section, page 1292, in particular.] In the instant, the

[3] Bartlett et al. Safety and immunogenicity of an HLA-based HIV envelope polyvalent synthetic peptide

C4-$V3_{MN}$ peptide that Bartlett et al. teaches has the same amino acid sequence as SEQ ID NO: 2, which has the following amino acid sequence: KQIINMWQEVGKAMYATRPNYNKRKRIHIGPGRAFYTTK. Bartlett et al. teaches the use of C4-$V3_{MN}$ to elicit an HIV-antigen specific immune response. Hence, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to combine the adjuvant composition of Ulrich et al. and Disis et al. with the HIV antigen of Bartlett et al. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to enhance the immunogenicity of the HIV antigen that Bartlett et al. teaches. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because the use of adjuvant to enhance the immunogenicity of antigens is routinely practiced in the art. Furthermore, the adjuvanting effects of 3-O-deacylated monophosphoryl lipid A or monophosphoryl lipid A and GM-CSF, together with a carrier or a diluent has been recognized in the art at the time the invention was made. Therefore, the claimed invention is obvious over the teachings of Ulrich et al., Disis et al. and Bartlett et al.

8. Claims 88, 98, 105, 109, 116, 160, 163-164 and 167 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ulrich et al. and Disis et al., in view of Bartlett et al., as applied to claims 88, 98 and 116.

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immunogen. AIDS, 1998, Vol. 12, No. 11, 1291-1300.

In response to the rejection, Applicant submits the same arguments presented in paragraph 6 of this office action, which is addressed by the Office in the same paragraph.

Additionally, Applicant argues that the skilled artisan would not be able to predict that the claimed adjuvant combination would elicit high titers and CTL responses. Applicant also submitted the teachings of Boon et al. to demonstrate a teaching away from the claimed invention. Applicant also used Boon et al. to support Applicant's assertion that not all combinations of adjuvant will work in combination to enhance the immune response to an antigen.

This argument has been considered, however, it is not found persuasive. In the instant case, nothing exists to evidence that one of ordinary skill in the art would not be able to make the claimed invention without a reasonable expectation of success. Both Ulrich et al. and Disis et al. teach of adjuvants that induces CTL responses. Ulrich et al. further discloses the synergistic effects of combining MPL with other adjuvants in inducing antibody responses. Furthermore, there does not exist any evidence showing that the higher titers and CTL responses observed by Applicant is unexpected. While it is noted that Applicant has presented the disclosure of Boon et al. as demonstrating that it teaches away from the use of GM-CSF with MPL. The teachings of this reference have been noted, however, any allegation of Boon et al. as teaching away from the claimed invention is moot for the rejection is not made over Boon et al. Additionally, it should be noted that this specific teachings of Boon et al. is limited to the addition of GM-CSF to a combination of MPL and QS21. It is in this context that Boon et al. notes

that GM-CSF does not enhance the effect of an adjuvant composition comprising MPL and QS21. The teachings of Boon et al. are not directed to the composition rendered obvious by Ulrich et al. and Disis et al.

Regarding Applicant's assertion that not all combinations of adjuvant will work in combination to enhance the immune response to an antigen, Applicant is reminded that absolute predictability is not the standard for an obviousness rejection. The standard for an obviousness rejection is a reasonable expectation of success. In the instant case, using the teachings of Ulrich et al. and Disis et al., the Office has clearly established a prima facie case of reasonable expectation of success. Additionally, Applicant is reminded that the function of an adjuvant is to enhance the immune response induced by an antigen. Thus, the administration of an antigen with any adjuvant, whether it is just MPL or GM-CSF or combination of MPL and GM-CSF, the immune response induced by the antigen would inherently be enhanced by the adjuvant.

As previously presented, claims 105, 109, 160, 163-164 and 167 are directed to the administration of the composition of claims 98 (as it pertains to claims 105 and 109) and 116 (as it pertains to claims 160, 163-164 and 167) to elicit an immune response in a subject. In the instant, claim 105 and 109 recite a direct dependency to claim 98, which depends on claim 88; and claims 160 and 164 recite a direct dependency to claim 116, which depends on claim 98. Additionally, claim 163 recites a dependency to claim 160; and claim 167 recites a dependency to claim 164. In addition to eliciting an immune response in the subject, claims 109 and 164 requires that the immune

response be a CTL response. Lastly, claims 163 and 167 require the antigen administered to have the amino acid sequence set forth in SEQ ID NO: 2.

The significance of Ulrich et al., Disis et al. and Bartlett et al., as applied to claims 88, 98 and 116, is discussed above. In the instant, Ulrich et al., Disis et al. and Bartlett et al. do not teach the administration of the composition of claims 98 and 116; however, as discussed above, the antigen of Bartlett et al. is a multideterminant peptide comprising T-helper epitopes from the fourth constant region (C4) of gp120 of HIV-1_{MN}, and T-helper, and cytotoxic T-lymphocyte HLA-B7-restricted; and B-cell neutralizing epitopes from the gp120 third variable region. Bartlett et al. teaches the administration of the multideterminant peptide to induce an HIV specific immune response. Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to administer the HIV antigen of Bartlett et al. with the adjuvant composition that Ulrich et al. and Disis et al. teaches. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to enhance the immunogenicity of the HIV antigen that Bartlett et al. teaches. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because the use of adjuvant to enhance the immunogenicity of antigens is routinely practiced in the art. Furthermore, the adjuvanting effects of 3-O-deacylated monophosphoryl lipid A or monophosphoryl lipid A and GM-CSF, together with a carrier or a diluent has been recognized in the art at the time the invention was made. Therefore, the claimed invention is obvious over the teachings of Ulrich et al., Disis et al. and Bartlett et al.

Additionally, the administration of the antigen of Bartlett et al. would necessarily induce a CTL response in the subject. As noted above, the antigen of Bartlett et al. contains CTL specific epitopes. Thus, the administration of said antigen would necessarily induce a CTL response in the subject.

Conclusion

9. No claims are allowed.

10. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571)272-0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Le/
Patent Examiner, Art Unit 1648

/E. L./